



THOMAS L. GARTHWAITE, M.D.
Director and Chief Medical Officer

COUNTY OF LOS ANGELES
DEPARTMENT OF HEALTH SERVICES
313 N. Figueroa, Los Angeles, CA 90012
(213) 240-8101

BOARD OF SUPERVISORS

Gloria Molina
First District

Yvonne Brathwaite Burke
Second District

Zev Yaroslavsky
Third District

Don Knabe
Fourth District

Michael D. Antonovich
Fifth District

November 17, 2005

The Honorable Board of Supervisors
County of Los Angeles
383 Kenneth Hahn Hall of Administration
500 West Temple Street
Los Angeles, California 90012

Dear Supervisors:

**TESTING FOR PRIMARY HIV INFECTION IN SERONEGATIVE
PATIENTS PROJECT NOTICE OF GRANT AWARD NO. 5 UA1 PS000061-02**
(All Districts) (3 Votes)

IT IS RECOMMENDED THAT YOUR BOARD:

1. Approve and instruct the Director of Health Services, or his designee, to accept Notice of Grant Award (NGA) No. UA1 PS000061-02 (Exhibit I) from the Federal Centers for Disease Control and Prevention (CDC) for the period effective September 30, 2005 through September 29, 2006 to support the Testing for Primary HIV Infection in Seronegative Patients project, in the amount of \$323,113.
2. Delegate authority to the Director of Health Services, or his designee, to accept subsequent NGAs, substantially similar to NGA No. UA1 PS000061-02, in an amount not to exceed 25% over the base award, for a maximum of two years, contingent upon availability of CDC funds and subject to review and approval by County Counsel, Chief Administrative Office and notification of Board offices.
3. Delegate authority to the Director of Health Services, or his designee, to accept amendments to NGAs with the CDC for a maximum of two years, which do not individually exceed 25% of the total amount of the NGA for each calendar year, and which do not materially alter the terms and conditions set forth under NGA No. UA1 PS000061-02, subject to review and approval by County Counsel, Chief Administrative Office and notification of the Board offices.

PURPOSE/JUSTIFICATION OF THE RECOMMENDED ACTIONS:

Board approval of the recommended actions will authorize the acceptance of grant funds from the CDC to support personnel and operating expenditures for the continued provision of Testing for

Primary HIV Infection in Seronegative Patients. The project provides assistance to the Department of Health Services' (DHS or Department) Sexually Transmitted Disease (STD) Program to determine the feasibility of implementing a program of early detection based on the detection of primary HIV infection which has important implications for preventing subsequent cases of HIV infection in high incidence areas.

FISCAL IMPACT/FINANCING:

The total program cost for Year 2 of the grant period, effective September 30, 2005 through September 29, 2006, is \$610,086, offset by \$323,113 in CDC funds and \$286,972 in County-in-kind contribution as detailed in Exhibit II.

Funding for this program is included in the FY 2005-06 Final Budget and will be requested in future fiscal years.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS:

Since 1956, the Federal government has provided assistance to the Department's STD Program by awarding grant funds, financial assistance and/or assigning federal government personnel as direct assistance to support services for the STD projects.

The STD Program submitted an application dated July 22, 2004 to the CDC for funding of the project "Testing for Primary HIV Infection in Seronegative Patients".

On September 23, 2004, the Department received NGA No. 1 UA1 PS000061-01 in support of the STD project. Funding restrictions of 50% (\$104,785) of the total funding was on hold pending Institutional Review Board (IRB) approval.

On February 1, 2005, the Board approved NGA No. 1 UA1 PS000061-01 in the amount of \$209,571, effective date of Board approval through September 29, 2005 to fund the subject project and other related recommendations.

On September 6, 2005, the Department received NGA No. 5 UA1 PS000061-02 in the amount of \$323,113 for the continued provision of the referenced project. A funding restriction of 25% (\$80,278) is pending approval from the IRB for the CDC and DHS. Research involving human subjects cannot begin until IRB approval is received.

County Counsel has approved the NGA (Exhibit I) as to form.

Attachments A and B provide additional information. Attachment B is the Grants Management Statement for grant awards exceeding \$100,000.

CONTRACTING PROCESS:

Not applicable to this action.

The Honorable Board of Supervisors
November 17, 2005
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IMPACT ON CURRENT SERVICES (OR PROJECTS):

Approval of the recommended actions will assist DHS in the continuation of an STD project with important implications for preventing subsequent cases of HIV infection in high incidence areas in Los Angeles County.

When approved, this Department requires three signed copies of the Board's action.

Respectfully submitted,



Thomas L. Garthwaite, M.D.
Director and Chief Medical Officer

TLG:kh
BLETC4078.kh.wpd

Attachments(4)

c: Chief Administrative Officer
County Counsel
Executive Officer, Board of Supervisors
Auditor-Controller

SUMMARY OF AGREEMENTS

1. **TYPE OF SERVICES:**

Sexually Transmitted Disease project to determine the feasibility of implementing a program of early detection based on the detection of primary HIV infection which has important implications for preventing subsequent cases of HIV infection in high incidence areas.

2. **AGENCY ADDRESSES, CONTACT PERSONS:**

Department of Health and Human Services - Public Health Service
Federal Centers for Disease Control and Prevention (CDC)
Procurement and Grants Office
2920 Brandywine Road, E-15
Atlanta, Georgia 30341-4146

Attention: Kang Lee, Grant Management Specialist
Acquisition and Assistance, Branch II

Telephone: (404) 498-1917 Facsimile: (404) 488-1920 e-mail address: kil8@cdc.gov

3. **TERM:**

Budget Period: September 30, 2005 through September 29, 2006

Project Period: September 30, 2004 through September 29, 2006

4. **FINANCIAL INFORMATION:**

The total program cost for Year 2 of the grant period, effective September 30, 2005 through September 29, 2006 is \$610,086, offset by \$323,113 in CDC funds and \$286,972 in County-in-kind contribution as detailed in Exhibit II.

Funding for this program is included in the FY 2005-06 Final Budget and will be requested in future fiscal years.

5. **PRIMARY GEOGRAPHIC AREAS TO BE SERVED:**

Countywide.

6. **DESIGNATED ACCOUNTABLE FOR PROJECT MONITORING:**

Peter R. Kerndt, M.D., M.P.H., Director, Sexually Transmitted Disease Control Program.

7. **APPROVALS:**

Public Health: John F. Schunhoff, Ph.D., Chief of Operations

Contracts and Grants Division: Cara O'Neill, Chief

County Counsel (approval as to form): Allison Morse, Deputy County Counsel

**Los Angeles County Chief Administrative Office
Grant Management Statement for Grants Exceeding \$100,000**

Department: Health Services

Grant Project Title and Description -Testing for Primary HIV Infection in Seronegative Patients

Early HIV diagnosis and medical intervention. The project will quantify the extent to which primary HIV infection in pre-seroconversion period is missed through current HIV testing measures. The results of the study will provide information regarding the feasibility of implementing a program of early detection based on detection of primary HIV infection with important implications for preventing subsequent cases of HIV infection in high incidence areas.

Funding	Program (Fed. Grant #/State Bill or Code #)	Grant Acceptance Deadline
Federal CDC	Notice of Grant Award No. 1 UA1	ASAP

Total Amount of Grant		\$323,113	County Match		N/A
Grant Period:	1	Begi	09/30/05	End Date:	09/29/06
Number of Personnel Hired -Grant		5	Full	3	Part 2

Obligations Imposed on the County When the Grant Expires

Will all personnel hired for this program be informed this is a grant funded program? Yes ☒ No ☐

Will all personnel hired for this program be placed on temporary ("N") items? ☒ No ☐

Is the County obligated to continue this program after the grant expires Yes ☐ No ☒

If the County is not obligated to continue this program after the grant expires, the Department will:

a). Absorb the program cost without reducing other services Yes ☐ No ☒

b). Identify other revenue sources Yes ☒ No ☐
Describe

c). Eliminate or reduce, as appropriate, positions/program costs funded by this grant. Yes ☒ No ☐

Impact of additional personnel on existing space: None -

Other requirements not mentioned above: None

Department

Date

11/16/05

***** NOTICE OF GRANT AWARD *****
 Issue Date: 08/31/2005

Department of Health and Human Services
 Centers for Disease Control and Prevention
 NATIONAL CENTER FOR HIV, STD, AND TB PREVENTION, CDC

 Grant Number: 5 UA1 PS000061-02

Principal Investigator: KERNDT, PETER REYNOLDS MD
 Project Title: Testing Primary HIV Infected in Seronegative Patients

DIRECTOR, STD PROGRAM
 COUNTY OF LOS ANGELES-DHS
 5555 Fergurson Drive, Room 100-50
 LOS ANGELES, CA 90022
 UNITED STATES

Budget Period: 09/30/2005 - 09/29/2006
 Project Period: 09/30/2004 - 09/29/2006

Dear Business Official:


The Centers for Disease Control and Prevention hereby awards a grant in the amount of \$323,113 (see 'Award Calculation' in Section I) to LOS ANGELES COUNTY HEALTH SERVICES DEPT in support of the above referenced project. This award is pursuant to the authority of and is subject to terms and conditions referenced below.

Acceptance of this award including the Terms and Conditions is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Award recipients are responsible for reporting inventions derived or reduced to practice in the performance of work under this grant. Rights to inventions vest with the grantee organization provided certain requirements are met and there is acknowledgement of CDC support. In addition, recipients must ensure that patent and license activities are consistent with their responsibility to make unique research resources developed under this award available to the scientific community, in accordance with CDC policy. For additional information, please visit <http://www.iedison.gov>.

If you have any questions about this award, please contact the individual(s) referenced in the information below.

Sincerely yours,


 Cheryl M. Maddux
 Grants Management Officer
 Centers for Disease Control and Prevention

See additional information below

SECTION I - AWARD DATA - 5 UA1 PS000061-02

AWARD CALCULATION (U.S. Dollars):

Salaries and Wages	\$166,558
Fringe Benefits	\$79,288
Personnel Costs	\$245,846
Supplies	\$12,756
Travel Costs	\$4,575
Other Costs	\$17,984
Federal Direct Costs	\$281,161
Federal F&A Costs	\$41,952
APPROVED BUDGET	\$323,113
TOTAL FEDERAL AWARD AMOUNT	\$323,113

FISCAL INFORMATION:

CFDA Number: 93.943

EIN: 1956000927A1

Document Number: UPS000061A

IC/ CAN / FY2005

PS/9213908 / 323,113

ADMINISTRATIVE DATA:

PCC: / OC: 41.4P /Processed: MADDUXC 050831 1044

SECTION II - PAYMENT/HOTLINE INFORMATION - 5 UA1 PS000061-02

For payment information see Payment Information section in Additional Terms and Conditions.

To report fraud, waste or abuse see Inspector General section in Additional Terms and Conditions.

SECTION III - TERMS AND CONDITIONS - 5 UA1 PS000061-02

This award is based on the application submitted to, and as approved by, the CDC on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in this Notice of Grant Award.
- The restrictions on the expenditure of federal funds in appropriations acts, to the extent those restrictions are pertinent to the award.
- 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- The PHS Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

Treatment of Program Income:
Additional Costs

TERMS AND CONDITIONS OF THIS AWARD

NOTE 1: INCORPORATION: Program Announcement Number 04119, entitled, "Testing for Primary HIV Infection in Seronegative Patients", the application dated 14 June 2005, any applicable statutes, regulations, and OMB Circulars, are made part of this award terms and conditions by reference.

NOTE 2: INDIRECT COST: The recipient maintains a 23.1726% indirect cost rate, which has been certified by the local Government unit (County of Los Angeles DHS Public Health Finance).

NOTE 3: HUMAN SUBJECTS: NOTICE: Under governing regulations, federal funds administered by the Department of Health and Human Services, shall not be expended for research involving human subjects, and individuals shall not be enrolled in such research without prior approval by the Office for Human Research Protections (OHRP) of an assurance to comply with the requirements of 45CFR46 to protect human research subjects. Whenever an institution receives funding from a DHHS agency award to support such research, the awardee institution bears the ultimate responsibility for protecting human subjects under the award. This restriction applies to all performance sites engaged in human subject research, whether domestic, foreign or international without OHRP-approved assurances, compliance for all performance sites must be ensured by the awardee.

NOTE 4: FUNDING RESTRICTION: Funds are restricted for human subjects as follows: A 25% or \$80,278 of the total funding has been restricted on this award pending IRB Approvals. Research involving human subjects cannot begin until the CDC Grants Management Officer receives written documentation of the following:
A copy of the IRB approval letter for each of the institutions must be received from:

Los Angeles Department of Health and CDC IRB

To register the IRB and apply for a FWA, contact the OHRP at
<http://ohrp.osophs.gov/irbasur.htm>

NOTE 5: REPORTING REQUIREMENTS:

(a) The Financial Status Report (SF 269) and
(b) a Final Progress Report are due to the CDC Grants Management Office within 90 days from the budget period ending at September 29, 2006. The original and two paper copies of both reports must be mailed to the Grants Management Specialist's mailing address shown in the NOTE 17 by no later than December 29, 2006. Several cautionary and additional instructions for preparation of the two reports are as follows:

(a) Financial Status Report (SF 269):
The CDC's reporting requirements in item 10 of SF 269 long or short form deviate from the original form instructions. CDC requires that amounts be entered only for column II for "This Period." Leave columns I and III, "Previously Reported" and "Cumulative" blank. Please do not leave the shaded area of the column II in blank.

(b) Final Progress Report:
This award is for the final year of the project period. The final progress report must contain a summary of the activities covering for the entire project period and include the contents as stated in the 45 CFR92.40.(b). The excerpts of the regulation are as follows:

- (2) Performance reports will contain, for each grant, brief information on the following:
 - (i) A comparison of actual accomplishments to the objectives established for the period. Where the output of the project can be quantified, a computation of the cost per unit of output may be required if that information will be useful.
 - (ii) The reasons for slippage if established objectives were not met.
 - (iii) Additional pertinent information including, when appropriate, analysis and explanation of cost overruns or high unit costs."
- (4) Grantees will adhere to the standards in this section in prescribing performance reporting requirements for subgrantees."

NOTE 6: HIV PROGRAM REVIEW PANEL REQUIREMENT: The recipient is reminded that all written materials, audiovisual materials, pictorials, questionnaires, survey instruments, websites, educational curricula and other relevant program materials have to be reviewed and approved by an established program review panel. A list of reviewed materials and approval dates must be submitted to the CDC Grants Management Officer.

NOTE 7: CORRESPONDENCE: All correspondence regarding this award must be identified with the award number as shown at the top right of this page.

NOTE 8: PRIOR APPROVAL: "ALL requests that require the prior approval in accordance with 45 CFR74.25 such as changes in budget, key employee, programmatic plans, etc. must bear the two signatures of both the recipient's authorized business official and the principal investigator or program director. Any request received with only one signature will not be accepted and returned to the recipient. In addition, any requests involving funding issues

must include a new proposed budget and a narrative justification of the requested changes.

NOTE 9: KEY PERSONNEL: In accordance with 45 CFR 74.25(c), for nonconstruction awards, recipients shall obtain prior approvals from the HHS awarding agency for one or more of the following program or budget related reasons: (1) Change in the scope or the objective of the project or program (even if there is no associated budget revision requiring prior written approval). (2) Change in the project director or principal investigator or other key persons specified in the application or award document. (3) The absence for more than three months, or a 25 percent reduction in time devoted to the project, by the approved project director or principal investigator.

Key Personnel are specified as follows:
Peter Kerndt, Director, Los Angeles County STD Program
Belinda Snguon, Acting Grants Manager

NOTE 10: PUBLICATIONS: Publications, journal articles, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, such as: This publication (journal article, etc.) was supported by Grant/Cooperative Agreement Number UAI/PS000061-02 from The Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention.

NOTE 11: EQUIPMENT AND PRODUCTS: To the greatest extent practicable, all equipment and products purchased with CDC funds should be American-made.

NOTE 12: ACKNOWLEDGMENT OF FEDERAL SUPPORT: When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all awardees receiving Federal funds, including and not limited to State and local governments and recipients of Federal research grants, shall clearly state (1) the percentage of the total costs of the program or project which will be financed with Federal money, (2) the dollar amount of Federal funds for the project or program, and (3) percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

NOTE 13: INSPECTOR GENERAL: The HHS Office Inspector General (OIG) maintains a toll-free number (1-800-HHS-TIPS [1-800-447-8477]) for receiving information concerning fraud, waste or abuse under grants and cooperative agreements. Information also may be submitted by e-mail to hhstips@oig.hhs.gov or by mail to Office of the Inspector General, Department of Health and Human Services, Attn: HOTLINE, 330 Independence Ave., SW, Washington DC 20201. Such reports are treated as sensitive material and submitters may decline to give their names if they choose to remain anonymous. This note replaces the Inspector General Contact information cited in previous notice of award.

NOTE 14: PAYMENT Automatic Drawdown: Payment under this award will be made available through the Department of Health and Human Services (HHS) Payment Management System (PMS). PMS is administered by the Division of Payment Management, Program Support Center, HHS. PMS will forward the DHHS Manual for Recipients Financed under the Payment Management System (PMS), PMS-270 and PMS-272 forms.

A. PMS correspondence, mailed through the U.S. Postal Service, should be addressed as follows:

Division of Payment Management
FMS/PSC/HHS
P.O. Box 6021
Rockville, MD 20852.

B. If a carrier other than the U.S. Postal Service is used, such as United Parcel Service, Federal Express, or other commercial service, the correspondence should be addressed as follows:

Division of Payment Management
FMS/PSC/HHS
Rockwall Building #1, Suite 700
11400 Rockville Pike
Rockville, MD 20852.

To expedite your first payment from this award, attach a copy of the Notice of

Grant/Cooperative Agreement to your payment request form.

Note 15: AUDIT FILING COMPLIANCE: An organization that expends \$500,000 or more in a year in Federal awards shall have a single or program-specific audit conducted for that year in accordance with the provisions of OMB Circular A-133, Audit of States, Local Governments, and Non-Profit Organizations. It must be completed and a data collection form, and reporting package shall be submitted within the earlier of 30 days after receipt of the auditor's report(s), or nine months after the end of the audit period. The audit report must be sent to: Federal Audit Clearing House, Bureau of the Census, 1201 East 10th Street, Jacksonville, IN 47132. Should you have questions regarding the submission or processing of your Single Audit package, contact the Federal Audit Clearinghouse at:
(301) 763-1551
(800) 253-0696
Or email: govns.fac@census.gov

Note 16: EPI/PROGRAM CONSULTANT TECHNICAL REVIEW FORM: The recipient must respond in writing to any weakness or required corrective action plans cited in the attached Technical Review, if applicable, and mail an original and two paper copies of the response report to the Grants Management Specialist by November 1, 2005.

NOTE 17: CDC CONTACT NAMES:

Grants Management Contact
Kang Lee, Grants Management Specialist
Centers for Disease Control and Prevention (CDC)
Procurement and Grants Office
2920 Brandywine Road E-15
Atlanta, Georgia 30341-4146
Telephone: (404) 498-1917
Fax: (404) 498-1920 or 1930
E-mail: kil8@cdc.gov

Programmatic Contact
Pragna Patel, Project Officer
Centers for Disease Control and Prevention (CDC)
Division of HIV/AIDS Prevention
Corporate Square, Bldg. 8, MS D-21
Atlanta, GA 30333
Telephone: 404-639-5248
Fax: 404-639-5257
E-Mail: jcg3@cdc.gov

Kang W Lee, Grants Specialist
Phone: 770-488-2733 Email: klee@cdc.gov Fax: 770-488-2670

SPREADSHEET

GRANT NUMBER: 5 UA1 PS000061-02

P.I.: KERNDT, PETER REYNOLDS

INSTITUTION: LOS ANGELES COUNTY HEALTH SERVICES DEPT

	YEAR 02
	=====
Salaries and Wages	166,558
Fringe Benefits	79,288
Personnel Costs	245,846
Supplies	12,756

YEAR 02

=====

Travel Costs	4,575
Other Costs	17,984
TOTAL FEDERAL DC	281,161
TOTAL FEDERAL F&A	41,952
TOTAL COST	323,113

**EPI / PROGRAM CONSULTANT
TECHNICAL REVIEW FORM**

Date: June 17, 2005

Grantee Name: Los Angeles County Department of Health Services

Program Announcement Number: 04119

Name of Study: Testing for Primary HIV Infection in Sero-negative Patients

Amount Requested: \$321,113

Amount Recommended / Funded: \$323,113

Name of Evaluator / Reviewer (print): Pragna Patel

Signature: _____

Compliance with Content Guidelines? (y/n): Y **Date:** June 17, 2005

Progress in Program or Study Objectives or Activities: Describe (by indicating the application's *Strengths* and *Weaknesses*) the current status of the Program or Activity.

Summary of Strengths: (please use bullets)

Applicant has adequately addressed objectives to meet the following performance goal:

1) To identify persons infected with PHI that would otherwise be missed by current HIV testing algorithms and to assess the feasibility and cost-effectiveness of pooled NAAT relative to second and third generation HIV antibody assays and rapid tests.

Specifically the following objectives are currently being addressed:

- 1) To order supplies and finalize consent and data collections forms.
- 2) To obtain CDC and LA County IRB approval
- 3) To finalize data codebooks and create LAPHL spreadsheets and STD program databases
- 4) To ensure all relevant personnel understand testing protocol.

The Principal Investigator (PI) has developed a draft laboratory protocol which was submitted to CDC for review on May 10th. Grantee and CDC are in the process of revising and finalizing the document.

The following performance goals remain to be addressed:

- 1) To describe the transmission and the epidemiology of PHI
- 2) To describe the outcomes of partner notification of persons with PHI
- 3) To describe antiretroviral resistance in persons with PHI
- 4) To assess transmission correlates and clusters using epidemiological and molecular approaches.

Summary of Weaknesses: (please use bullets)

I cannot identify significant weaknesses within this well-prepared application.

However, the study timeline has shifted since submission of the study outline. This was largely due to external factors, such as the Gen-Probe litigation (precluding the use of Procleix for NAAT), which delayed the design of this study.

Proposed Changes / Modifications in Objectives or Program Plan: (Describe the proposed changes in objectives or plans and the grantee's ability to achieve them)

Supplemental funding was made available to current grantees for additional work which involves individual NAAT on all enzyme immunoassay-repeatedly reactive (EIA-RR) and Western Blot (WB) positive specimens. Individuals who are EIA/WB positive and NAAT negative will be invited to participate in a short longitudinal study that involves brief interviews and whole blood collection at 3 and 6 months from the date of their first EIA/WB positive and NAAT negative result. The purpose of the supplement is to assess the role of NAAT in HIV diagnostics.

The grantee has submitted a proposal for the supplement and has adequately described their plan to achieve this goal. Given their thoughtful consideration and commitment to the project, I believe that they are more than able to achieve this goal.

Budget Issues: (Describe any budget concerns [yours or grantees] that may affect the study or program plan)

Total requested budget \$321,113. See marked up budget for detailed breakdown and review.

Recommendation: (Provide recommendations for improving the objectives, methodology, activities, and other aspects of the study or program)

The Los Angeles County Department of Health Services has made superior progress thus far in the design of this project. I would recommend continued strong support of their overall goal of screening for Primary HIV Infection in sero-negative persons in Los Angeles County.

COUNTY OF LOS ANGELES - DEPARTMENT OF HEALTH SERVICES
PUBLIC HEALTH SERVICES - DISEASE CONTROL
SEXUALLY TRANSMITTED DISEASE PROGRAM

TESTING FOR PRIMARY HIV INFECTION IN SERONEGATIVE PATIENTS

PROGRAM ANNOUNCEMENT 04119
ESTIMATES OF YEAR 2 BUDGET
Grant Term: SEPTEMBER 30, 2005 THROUGH SEPTEMBER 29, 2006

DESCRIPTION	Monthly Salary 9/30/05-12/31/05	Monthly Salary 1/1/06-9/29/06	# Of FTEs	# Of Months	% Time	Salary Requested	Grant Budget	County In-Kind	Total Program Cost
PERSONNEL SERVICES									
A. Full-Time Employees									
Director, Peter Kerndt, MD, MPH	\$ 12,870.00	\$ 13,191.93	1	12	15%	\$ -	\$ -	\$ 67,310	\$ 67,310
Epidemiologist, Lisa V. Smith	\$ 5,742.14	\$ 5,885.64	1	12	100%	\$ 70,197	\$ 70,197	\$ -	\$ 70,197
Epidemiologist, Marjan Javanbakht	\$ 5,742.14	\$ 5,885.64	1	12	25%	\$ -	\$ -	\$ 34,740	\$ 34,740
Public Health Investigator, TBH	\$ 4,136.91	\$ 4,240.33	1	9	100%	\$ 38,163	\$ 38,163	\$ -	\$ 38,163
Information Systems Analyst II, Chona Felix	\$ 5,294.00	\$ 5,426.35	1	12	20%	\$ -	\$ -	\$ 29,858	\$ 29,858
Systems Aid, Harry Rollins	\$ 3,202.27	\$ 3,282.32	1	12	15%	\$ -	\$ -	\$ 16,748	\$ 16,748
Community Services Counselor, TBH	\$ 3,150.20	\$ 3,259.70	1	12	100%	\$ 38,878	\$ 38,878	\$ -	\$ 38,878
Intermediate Typist Clerk, Mitsue Wakabayashi	\$ 2,548.09	\$ 2,611.79	1	12	15%	\$ -	\$ -	\$ 13,327	\$ 13,327
Data Analyst, Marian Eldanaby	\$ 2,913.00	\$ 2,985.82	1	12	25%	\$ -	\$ -	\$ 17,624	\$ 17,624
Health Education Assistant, TBH	\$ 3,411.82	\$ 3,497.12	1	9	100%	\$ 31,474	\$ 31,474	\$ -	\$ 31,474
Total Full-Time Salaries						\$ 178,712	\$ 179,607	\$ -	\$ 358,319
Salary Savings (5%)						\$ (8,936)	\$ (8,980)	\$ -	\$ (17,916)
Adjusted Salaries						\$ 169,776	\$ 170,627	\$ -	\$ 340,403
Employee Benefits (@ 43.7957%)						\$ 74,355	\$ 74,727	\$ -	\$ 149,082
B. Part-Time Employees						\$ -	\$ -	\$ -	\$ -
None						\$ -	\$ -	\$ -	\$ -
TOTAL PERSONNEL SERVICES						\$ 244,131	\$ 245,354	\$ -	\$ 489,485
OPERATING EXPENSES									
Supplies:									
Laboratory Supplies (cryovials, cryoboxes, tiger top tubes, pipette tips, freezer labels, versil dry paper mails)						\$ 9,417	\$ 9,417	\$ -	\$ 9,417
Specimen Shipping Boxes (16 cases @ \$208.69 per case)						\$ 3,339	\$ 3,339	\$ -	\$ 3,339
						\$ 12,756	\$ 12,756	\$ -	\$ 12,756
Travel:									
Travel (2 trips for P.I. and Project Director)						\$ 3,400	\$ 3,400	\$ -	\$ 3,400
Other:									
Printing/Duplication						\$ 800	\$ 800	\$ -	\$ 800
Incentives (10 participant x 10 visits x \$30 per visit = \$3,000 and 50 NAAAT participants x \$100 = \$5,000)						\$ 8,000	\$ 8,000	\$ -	\$ 8,000
Bilingual Bonus (\$100 per month x 9 mos x 2 staff = \$1,800 and \$100 per month x 12 mos x 1 staff)						\$ 1,800	\$ 1,800	\$ -	\$ 1,800
Mileage (524 miles per mo x 12 mos @ 0.45/mile)						\$ 2,830	\$ 2,830	\$ -	\$ 2,830
Mail/Postage/Shipping						\$ 7,984	\$ 7,984	\$ -	\$ 7,984
						\$ 21,414	\$ 21,414	\$ -	\$ 21,414
TOTAL OPERATING EXPENSES						\$ 37,570	\$ 37,570	\$ -	\$ 37,570
INDIRECT COST (@ 23.1726% on Total Salary and Wages)						\$ 41,412	\$ 41,619	\$ -	\$ 83,031
TOTAL BUDGET						\$ 323,113	\$ 286,973	\$ -	\$ 610,086

Testing for Primary HIV Infection in Seronegative Patients

**BUDGET JUSTIFICATION
SEPTEMBER 30, 2005 – SEPTEMBER 29, 2006**

PERSONNEL

Peter R. Kerndt, MD, MPH (0.15 FTE) Principal-Investigator in-kind

Dr. Kerndt will work closely with the Centers of Disease Control and Prevention (CDC), and other collaborative sites including the 14 Los Angeles County (LAC) Sexually Transmitted Disease clinics, LAC Sexually Transmitted Disease Program Mobile Testing Unit (MTU), and the Los Angeles Gay and Lesbian Center (LAGLC) to ensure that all aspects of the project are completed, including site operations, data analysis, and Institutional Review Board (IRB) approval. Dr. Kerndt will be responsible for oversight of all testing of HIV specimens, shipping to the New York Public Health Laboratory and CDC for HIV RNA testing and phylogenetic testing (respectively), and follow-up of all HIV RNA positive clients enrolled in the study. Dr. Kerndt will be responsible for direct supervision of the Project Director and will monitor the project for protocol development and study design.

Dr. Kerndt served as Director of the HIV Epidemiology Program of the Los Angeles County (LAC) Department of Health Services (DHS) between 1987 and 1999. He is currently Director of the LAC Sexually Transmitted Disease Program (STDP). Dr. Kerndt has extensive experience coordinating and conducting multi-site, cross-sectional and diagnosis of HIV and AIDS related disease studies.

Lisa V. Smith, MS DrPH (1.0 FTE x 12 months) Project Director/Epidemiologist \$70,197

Dr. Smith will be responsible for implementation of specific research protocols, including obtaining IRB and Federal Wide Assurance (FWA) approvals, and assuring their adherence. She will act as liaison to the study sites and provide direct supervision of the study protocol. She will be in daily contact with the study sites, laboratory staff, Public Health Investigators (PHIs), and the student workers to ensure that the study is being implemented in a manner that is minimally intrusive to clinic flow. She will be responsible for supervising project staff including Laboratory Assistant and the Student Worker, and will have administrative responsibility for all other project staff.

Dr. Smith will directly supervise the collection of blood samples, delivery of specimens to the LAC Public Health Laboratory (PHL) for testing, and the shipment of specimens on a daily basis to the New York Public Health Laboratory. She will act as liaison to the study sites to ensure all study data (informed consents, patient intake forms, HIV EIA test results, HIV RNA test results) is being delivered to the headquarters routinely. In addition, she will oversee a data quality control program to assure the collection of complete and accurate study data. She will ensure that all HIV RNA positive results are reported back to the study participants in a timely manner and the clients are enrolled in case management.

Marian Javanbakht, PhD[c] (0.25 FTE) Epidemiologist in-kind

Ms. Javanbakht will work with the STD Program liaison to the Los Angeles Gay and Lesbian Center (LAGLC) and who in turn will work closely with their Epidemiologist to prepare monthly submissions of patient demographic, behavioral, and testing data for electronic transfer to the STD Program. In addition, she will configure the master database for management of data elements in accordance with data-file specification provided by the CDC, as well as, merge monthly Public Health Information System (PHIS) datasets with the laboratory results from MISYS and download files into the master database. She will also assist the PHI in designating 50 EIA-RR/WB-positive, NAAT-negative persons for the subsequent follow-up.

TBH (1.0 FTE x 9 months) Public Health Investigator (PHI) \$38,163

This position will function as the dedicated PHI on this project. The PHI will coordinate patient follow-up of EIA-negative, NAAT-positive patients during the first phase of the study, which includes drawing additional tubes for confirmatory testing, administering baseline and follow-up questionnaires, and making referrals to STD Program Partner Counseling and Referral Services (PCRS). He/she will coordinate the

Principal Investigator/Program Director (Last, First, Middle): Kerndt, Peter, Reynolds

short longitudinal study that involves brief interviews and whole blood collection from patients who are EIA-RR/WB positive and NAAT negative, for which we are requesting supplemental funding.

In addition, the PHI will work closely with the STD Program Clinic liaison to train clinic managers, HIV counselors, PHIs regarding the protocol for data and specimen collection and patient receipt of NAAT test results.

Chona Felix (0.20 FTE) Information Systems Analyst II in-kind
Ms. Felix will coordinate the monthly transmission of electronic files from LAGLC and Public Health Information System (PHIS).

Harry Rollins (0.15 FTE) Systems Aid in-kind
Mr. Rollins will maintain SAS-version of MISYS database, which is merged to the PHIS and Mobile Testing Unit databases. Her duties will include data cleaning and data tabulation of MISYS database.

Lashawnda Royal (1.0 FTE x 12 months) Community Services Counselor \$38,798
Ms. Royal will serve as the Community Services Counselor (CSC) and will be responsible for coordinating pick up of informed consent and intake forms from the various study sites. She will also deliver data from the PHL to the study Project Director at the STDP.

The Community Services Counselor will collate, check for completeness, enter files, and maintain study-related records in a secure location. The responsibilities of the CSC will be dictated by daily events to assure that the study protocol is carried out efficiently. These may include photocopying informed consent forms, transporting study supplies, mailing data/IRB documents, and maintaining communication with the Laboratory Assistant. This position will report directly to the Project Director.

Mitsue Wakabayashi (0.15 FTE) Intermediate Typist Clerk in-kind
Ms. Wakabayashi will serve as data entry staff for the study and will scan STD clinic and Mobile Testing Unit intake forms into ACCESS, file informed consents, and assist in entering HIV test results from PHL and HIV RNA test results from the CDC-designated laboratory.

Marian Eldahaby (0.25 FTE) Data Analyst in-kind
Ms. Eldahaby will maintain the Mobile Testing Unit database. Her duties will include data cleaning and data tabulation this database.

TBH (1.0 FTE x 9 months) Health Education Assistant \$31,474
The Health Education Assistant for this study will be responsible for training and familiarizing counselors and providers at the LAC Health Centers, LAGLC and STDP Mobile Testing Unit with the Primary Infection Protocol. Specifically with the new counseling messages during the pre-test counseling regarding the new pooling strategy for HIV testing and during the post-test counseling about the meaning of the test result which determines the clients Acute Infection status. The Health Education Assistant will oversee all the additional blood draws and consent process at all the recruitment sites; they will function as the primary liaison between the clinic staff and STDP; will oversee ordering of all the necessary laboratory supplies; prepare presentations and reports alongside the study Project Director to present to various clinic staff about the status and the progress of the Primary HIV Infection Project.

SUBTOTAL FULL TIME PERSONNEL	\$178,712
SALARY SAVINGS @ 5%	(\$8,936)
ADJUSTED FULL TIME SALARIES	\$169,776
SUBTOTAL PART TIME PERSONNEL	\$ 0
FRINGE BENEFITS (43.7957% for full-time employees)	\$74,355
I. TOTAL PERSONNEL COSTS	\$244,131

OPERATING EXPENSES

II. CONSULTANT COSTS

N/A

III. EQUIPMENT COSTS

N/A

IV. SUPPLIES

\$12,756

Laboratory Supplies

\$9,417

Funds are being requested to cover the cost of lab supplies for the duration of the project. Based on the sample size calculations and eligibility criteria we propose to ship a total of 28,479 collected specimens to a CDC designated laboratory for HIV RNA testing. Specimens will be collected from STD clinics, STDP Mobile Testing Unit, Men's Central Jail and LAGLC for a total of 12 months. Sample collection activities are estimated to start during the last six months of year one after the project has received local and national IRB approval.

The following laboratory supplies are needed for the duration of this project. Tiger tops are needed in order for the lab at LAGLC to collect an extra blood sample because they do not routinely send their specimens through LAC PHL. The cryovials will be used to store organisms. Cryoboxes will be used for the storage of cryovials. Pipette tips will be needed for aliquoting specimens to cryovials for shipment to a CDC designated laboratory. Freezer labels will be used to re-label the cryovials before they are packaged for shipment. Laboratory staff utilizes dry mats to prevent spillage of blood onto lab counters. Dry ice will be used to preserve lab specimens during shipment.

- 29 boxes of cryovials (1,000/box)
- 88 cases of cryoboxes (324/case)
- 67 cases of tiger tops (100/case) (*LAGLC only*)
- 57 boxes of pipette tips (500/box)
- 19 boxes of freezer labels (1500/box)
- 2 cases of dry mats (350/case)
- 2 cases of dry ice

Above estimates are for the full 12 months of sample collection.

Specimen Shipping Containers

\$3,339

In compliance with the requirements of national and international regulations for surface and air transportation of infectious substances, we are requesting funds for the cost of shipping containers. This package system is necessary because it meets all requirements of ICAO/IATA Packing Instruction 602, Infectious substances, and all surface and air transportation guidelines. The package includes insulated containers, shipping labels, and a box for shipment. We will need 8 packages in order to ship specimens 5 days a week taking into consideration the turn around time for empty boxes to return to Los Angeles, California. (16 cases @ \$208.69 per case)

V. TRAVEL

\$3,400

Travel funds are requested for the principal investigator and project staff to attend several protocol development and investigators meeting in Atlanta, GA. Personnel who travel will be determined by the PI and according to the needs of the study development phase and CDC requests. According to study specifications and Los Angeles County Department of Health Services reimbursement guidelines, trips are budgeted at round trip airfare per traveler, hotel/meals per day, mileage and parking reimbursement at the home airport, telephone expenses, and ground transportation at the destination city. Travel funds per person are estimated at \$850 per trip (airfare @ \$515/ 1 night hotel stay @ \$175 night = \$175; 2 days per diem allowance for meals @ \$60 per day = \$120; incidental expenses at \$20/day = \$40). Total travel funds requested for 2 trips per staff x 2 staff @ \$850 = \$3,400.

VI.	PATIENT CARE COSTS	N/A
VII.	ALTERATIONS/RENOVATIONS	N/A
VIII.	OTHER EXPENSES	\$21,414
	<u>Printing/Duplication</u>	<u>\$800</u>
	Funds requested are for anticipated costs related to printing and duplication. Large amounts of photocopying of surveys, materials, and consent forms will be required for this project given the substantial sample size of the study. Paper, toner for staff printers and the photocopy/fax machine, and related supplies such as staples, will be required. The estimated cost for printing/duplication supplies for year one is \$800.	
	<u>Incentives</u>	<u>\$8,000</u>
	Funds are requested to provide monetary incentives for PHIs participating in subsequent interviews and blood draws.	
	<u>Bilingual Bonus</u>	<u>\$1,800</u>
	Funds for the Spanish speaking Community Services Counselor, Public Health Investigator, and Health Education Assistant during pre and post test sessions (\$100 per mo x 12 mos x 1 staff, and \$100 per mo x 9 mos x 2 staff).	
	<u>Mileage</u>	<u>\$2,830</u>
	Mileage is requested for project related mileage for the Public Health Investigator, Health Education Assistant and the Community Services Counselor. Logistics of the study necessitate the transport of HIV risk assessment surveys, informed consent forms and laboratory supplies between the performance sites and the LAC PHL. According to mileage policy for the Los Angeles County STD Program, staff travel for study-related purposes is reimbursed at \$0.45/mile. Staff travel for the proposed project is estimated at approximately 524 miles per mo x 12 months @ \$0.45 per mile.	
	<u>Mail/Postage/Shipping</u>	<u>\$7,984</u>
	Shipping costs are incurred five days a week to ship specimens to the CDC designated laboratory for HIV RNA testing. The estimated cost for shipping for is \$7,984 at 250 shipments per yr x 31.93 per delivery.	
IX.	SUBTOTAL DIRECT COSTS (Personnel + Operating Expenses)	\$221,701
X.	SUBCONTRACTUAL COSTS	\$0
XI.	TOTAL DIRECT COSTS	\$281,701
	[TOTAL INDIRECT COSTS at 23.1726%]	\$41,412
XII.	TOTAL FUNDS REQUESTED	\$323,113